

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

In re Application of:)	
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Campbell et al.)	Group Art Unit: 1632
)	
Application No.: 09/225,233)	Examiner: D. Crouch
)	
Filed: January 4, 1999)	Confirmation No.: 2711
)	
For: QUIESCENT CELL)	
POPULATIONS FOR NUCLEAR)	
TRANSFER)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

BRIEF REGARDING EFFECT OF *MYRIAD* DECISION

In an Order dated November 5, 2012, the Patent Trial and Appeal Board authorized Appellant to file a Brief regarding the effect of the Decision of the Court of Appeals for the Federal Circuit in the “*Myriad*” case, *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (pet. cert. 25 September 2012) on the issues before the Board. This Brief explains the relevance of the *Myriad* decision to the pending Appeal.

Appellant's claims on appeal were rejected by the Examiner under 35 U.S.C. § 101 for being directed to nonstatutory subject matter. Since Appellant's filed the Appeal in this case, the Court of Appeals for the Federal Circuit decided *Association for Molecular Pathology v. U.S. Patent and Trademark Office* ("Myriad"). The decision in *Myriad* is relevant to the Examiner's rejection under 35 U.S.C. § 101 in the present Appeal.

In *Myriad*, the court examined a claim reciting, "An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2" for patentability under 35 U.S.C. § 101. At 1309. The court found that claims directed to an isolated DNA were directed to patent-eligible subject matter under 35 U.S.C. § 101. *Id.* at 1326. Under the reasoning set forth in the *Myriad* decision, Appellant's claims to clones are similarly directed to patent-eligible subject matter.

The court's opinion contains an expansive view of the scope of patentable subject matter under 35 U.S.C. § 101. *Id.* at 1326-1333. The court found that, although an isolated DNA contains the same genetic information as a naturally-occurring DNA, the isolated DNAs are different molecules from DNA that exist in nature because isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical

identity. *Id.* at 1328. Similarly, Appellant's claimed clones are different from mammals that exist in nature because Appellant's clones result from human intervention to isolate the genetic information of a mammal from sexual reproduction, imparting on that clone a distinctive identity. That is, the clone has a single parental donor with the same genetic information. This feature makes the clone distinct from every other mammal in nature.

In coming to its conclusion regarding patentability, the court relied on the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* as setting out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules. *Id.* at 1326-1328. As the Federal Circuit explained, in *Chakrabarty*, the claimed bacteria had a trait possessed by no single naturally occurring bacterium and of significant use in more efficiently treating oil spills. *Id.* at 1327. The court further noted that the Supreme Court found that the "claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.* The Court thus concluded that what distinguished Chakrabarty's oil-degrading bacteria from the mixed cultures claimed in *Funk Brothers*, and made the former patent-eligible, was that Chakrabarty's bacteria had "markedly different characteristics

from any [bacterium] found in nature” based on the efforts of the patentee.
Id.

Based on this framework, the Federal Circuit identified one distinction between products of nature and human-made invention for purposes of 35 U.S.C § 101: a change in the claimed composition’s identity compared with what exists in nature. *Id.* at 1327-1328. Appellant’s claimed clones have such a distinction. They are “clones.” “Clones” do not exist in nature, just as “isolated” DNAs do not exist in nature. Appellant’s clones have a single parental entity, the donor mammal, from which all of their genetic information has been derived. They exist at a later time than their parental donor mammals. Based on this distinction, Appellant’s clones are directed to patentable subject matter.

In its decision, the Federal Circuit referred to drawing a line between compositions that, even if arrayed in useful combinations or harnessed to exploit newly discovered properties, have similar characteristics as in nature, and compositions that human intervention has given “markedly different,” or “distinctive,” characteristics. *Id.* at 1328. Applying this test to isolated DNAs, the court found the claims to isolated DNAs drawn to patent-eligible subject matter because the claims cover molecules that are

markedly different, have a distinctive chemical structure and identity, from those found in nature:

It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form-as distinctive chemical molecules-from DNAs in the human body, *i.e.*, native DNA. Natural DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each of those DNA molecules is condensed and intertwined with various proteins, including histones, to form a complex tertiary structure known as chromatin that makes up a larger structural complex, a chromosome. *See supra*, Figure 3. Inside living cells, the chromosomes are further encapsulated within a series of membranes and suspended in a complex intracellular milieu.

Isolated DNA, in contrast, is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. For example, the *BRCA1* gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides. Similarly, *BRCA2* in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. In contrast, isolated *BRCA1* and *BRCA2*, with introns, each consists of just 80,000 or so nucleotides. And without introns, *BRCA2* shrinks to approximately 10,200 nucleotides and *BRCA1* to just around 5,500 nucleotides. Furthermore, claims 5 and 6 of the '282 patent cover isolated DNAs, *e.g.*, primers or probes, having as few as fifteen nucleotides of a *BRCA* sequence. Accordingly, *BRCA1* and *BRCA2* in their isolated states are different molecules from DNA that exists in the body; isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.

Id. at 1328.

The same applies to Appellant's clones. They are not purified forms of natural materials, but are distinct chemical entities obtained by human intervention. Appellant's clones could not exist without human intervention. They have a single parental entity, the donor mammal, from which their genetic information has been derived. This feature contrasts with all naturally-occurring mammals, which derive their genetic information from two mammals, namely, a mother and a father. In nature, genetic information is linked to mammalian sexual reproduction, which alters the identity of this information during each round of sexual reproduction, with each progeny receiving half of its genetic information from its mother and half from its father. Prior to Appellant's invention, it was not possible to separate the transfer of genetic information to progeny mammals from mammalian sexual reproduction. Appellant's invention changed this. Through human intervention, the clone has been isolated from the normal process of sexual reproduction. In this way, the alteration of genetic information by each round of sexual reproduction has been averted. All of the genetic information of the donor mammal, instead of just 50%, is received by the progeny. Thus, Appellant's clone is a distinct entity that is obtained by human intervention.

The Federal Circuit further found that the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material. *Id.* at 1330. Similarly, the patent eligibility of Appellant's clones is not negated by the fact that it has similar informational properties to its donor mammal. Although the genetic information of Appellant's clone is similar to that of its donor mammal, that information is now in a distinct form of a different mammal, the clone, that would not exist without human intervention. Under the Federal Circuit's expansive reading of 35 U.S.C § 101 in *Myriad*, Appellant's claimed clone is patent-eligible subject matter.

The Federal Circuit's decision further supports the patentability of Appellant's claims under 35 U.S.C. § 101 in its discussions of the difference between patentable and non-patentable subject matter. *Id.* at 1330-1332. The court stated, "It is the difference between knowledge of nature and reducing a portion of nature to concrete form, the latter activity being what the patent laws seek to encourage and protect." *Id.* at 1331. Appellant's clones are not the result of the knowledge of nature since nature does not produce clones of pre-existing mammals. Rather, Appellant's clones reduce a portion of nature, a single donor mammal's genetic information, to a concrete form, a clone with the intact genetic

information of the donor mammal. This difference further supports that Appellant's clones are patentable subject matter.

The following conclusion by the Federal Circuit in *Myriad* applies equally to Appellant's claimed clones: "Everything and everyone comes from nature, following its laws. But the compositions here are not natural products. They are the products of man, albeit following, as all materials do, laws of nature." *Id.* at 1331. For all of the preceding reasons, the rejections under 35 U.S.C. § 101 should be reversed.

Respectfully submitted,

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